In Vivo Application of Novel and Commercially Available Bioabsorbable Implants for Tibial Fixation of Anterior Cruciate Ligament Reconstruction Grafts

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Introduction: Successful restoration of anterior cruciate ligament (ACL) function with soft tissue grafts requires fixation to pre-maintain stifte stability through graft ligamentization and incorporation. The tibial fixation is the weakest link of a femur-graft-tibia construct after ACL reconstruction. A variety of autograft fixation devices are available, and bioabsorable devices are an alternative to standard implants. The purpose of this study was to establish the in vivo function of a novel, bioabsorbable device (GraftGrab, Tesa Medical, Inc., Worcester, MA) to affect hamstring graft fixation to the tibial surface. The device allows graft fixation in a single fluid motion following graft tensioning. We hypothesized that post-operative tibial translation, surgical recovery, graft incorporation, and mechanical properties of graft-implant constructs would be indistinguishable from a commercially available, bioabsorbable screw and washer (Bio-Post and Spiked Washer, Arthrex, Inc., Naples, FL) (Fig. 1).

Methods: This study was performed in accordance with Institutional and NIH regulations governing the treatment of vertebrate animals. Fourteen normal adult dogs were assigned to two cohorts (n=7/cohort): 1) GraftGrab (GG); or 2) BioPost (BP) tibial fixation. Briefly, a hamstring graft was harvested from the gracilis, semimembranosus, and cranial tibialis fascia. The graft was trimmed, twisted to 4.5 mm in diameter and wrapped in a Chinese finger trap of #2 Vicryl. The native ACL was excised. The graft was placed through 4.5 mm bone tunnels from the medial aspect of the tibial to the insertion point of the cranial cruciate ligament and from the intra-articular origin of the ACL to just lateral to the proximal aspect of the lateral trochlear ridge. It was secured on the femoral side with an Endobutton (Smith & Nephew). Grafts were tensioned and fixed to the medial tibia with a GG or BP.

In vivo assessments consisting of objective lameness evaluation, knee translational stability, and computed tomography were performed before and 4 and 8 weeks after surgery. Tibial graft constructs were tensioned to failure to determine failure loads and energies were determined. Radiographs were performed without and during force application. Posterior, anterior, and total translation of the tibia was objectively measured on digital radiographs. Peak vertical force (PVF) and vertical impulse (VI) from force platform gait analysis were normalized to body weight. Ex vivo evaluations consisted of mechanical testing of each tibial-graft construct and microstructure of graft integration into the tibial bone tunnel 8 weeks after surgery. Tibia-graft constructs were tested in tension with a single cycle under axial load. Stiffness, yield, and failure loads and energies were determined. Tissues were then fixed in formalin, paraffin embedded, sectioned and stained with H&E and Masson’s Trichrome. Graft incorporation was subjectively assessed with light microscopy.

Results: Grafts were intact in all dogs but one GG animal in which partial (15%) graft disruption was apparent (Fig. 2). Peak vertical force was significantly greater for control limbs versus limbs containing implants 4 and 8 weeks after surgery (Fig. 3). Peak vertical force was significantly lower for limbs containing implants 4 and 8 weeks after surgery compared to preoperative values, and values were significantly lower 4 versus 8 weeks after surgery. Vertical impulse outcomes were identical with the exception that VI in BP limbs did not increase significantly between 4 and 8 weeks in contrast to GG limbs. There were no significant differences between in posterior, anterior or total tibial translation between implant cohorts at any time point (Fig. 3). Posterior tibial translation was significantly greater 8 weeks after surgery compared to pre-surgical values in the BP treatment group. There were no differences in graft or bone tunnel length, diameter, or surface area between groups or time points.

Discussion: Based on these results, hamstring graft ACL reconstruction fixation with bioabsorbable implants is an option for treatment of ACL deficient knees. Tibial cortical fixation with GG bioabsorbable implants is indistinguishable from a commercially available device, the BP, 4 and 8 weeks after implantation. Though differences between in vivo outcomes did not achieve statistical significance, sustained gait abnormalities and increased posterior tibial translation observed in the BP cohort were not observed in the GG cohort, suggesting a more stable GG construct. GG application requires fewer surgical procedures than the BP which may contribute to reduced costs and patient morbidity. These results support the GG as a mechanism of hamstring graft fixation to the tibia with procedural advantages over current implants.

Significance: The information contained in this study contributes to the existing body of knowledge surrounding tibial fixation of soft tissue ACL reconstructions. Specifically, a comprehensive study of the in vivo graft incorporation properties of a novel bioabsorbable device that has significant application advantages over existing devices is presented.